# Changes to the National Immunisation Programme

# Dr Brenda Corcoran National Immunisation Office





# Objectives

- To describe the new primary childhood immunisation (PCI) schedule
- To discuss the role out of the new changes and information materials available
- To discuss issues relating to the HPV vaccination programme





All babies born on or after 1st October 2016 will be offered the new PCI schedule

New schedule to start on 1<sup>st</sup> December 2016 (at 2 months of age)





Change	When
Addition of meningococcal B (MenB) vaccine	2, 4 and 12 months
Addition of rotavirus vaccine	2 and 4 months
Timing of MenC1	from 4 to 6 months
Timing of PCV3	from 12 to 13 months
Replacement of Hib and MenC with Hib/MenC (2 injections to 1 injection)	13 months





	Current Schedule		Babies born	
			on or after 1st October 2016	
Age (months)	Vaccine	No of injections	Vaccine	No of injections
2	6in1 + PCV	2	6in1 + PCV + MenB + Rotavirus	3
				+ oral vaccine
4	6in1 + MenC	2	6in1 + MenB + Rotavirus	2
				+ oral vaccine
6	6in1 + PCV	2	6in1 + PCV + MenC	3
12	MMR + PCV	2	MMR + MenB	2
13	MenC + Hib	2	Hib/MenC + PCV	2





From1st October 2016 until at least November 2017

- 2 schedules in place
- the old (current) schedule
- the new schedule





# Meningococcal B (MenB) disease

- Caused by Neisseria meningitidis.
- Most common and serious clinical presentations
  - meningitis and septicaemia
- An important clinical and public health problem
  - rare but serious
  - disease onset is sudden and often dramatic
- A significant case fatality rate ~10%
- 1 in 10 survivors have long term complications including
  - brain damage, deafness, epilepsy, limb/digit loss, cognitive deficit



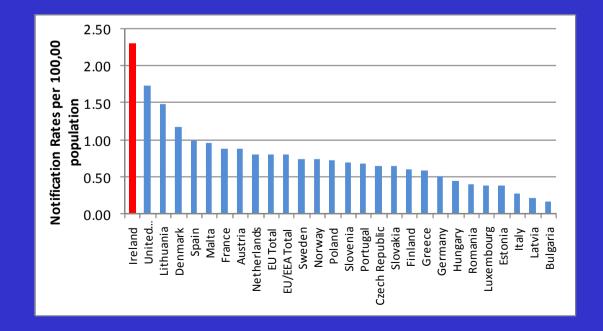


# Meningococcal B (MenB) disease

- Most common in infancy and early childhood (0-4 years)
- A second smaller peak of incidence in adolescents and young adults
- Ireland has one of the highest notification rates of invasive meningococcal disease (IMD) in Europe

Confirmed cases in the EU/EEA, 2008-2012

Source: HPSC







# MenB Vaccine

- A recombinant multi-component vaccine – Bexsero (GSK)
- NOT a live vaccine
- Safe and effective
- ~88% strains covered
- Widely given across Europe
- Introduced into the UK immunisation schedule in 2015
- Schedule
  - 2 + 1 schedule (not 3 +1 as per SmPC)







# MenB Vaccine Contraindications/ Precautions

#### Contraindications

- Anaphylactic reaction to a previous dose of vaccine
- Anaphylactic reaction to any constituent of vaccine including kanamycin and latex

#### **Precautions**

- Acute severe febrile illness
  - defer until well
- Known coagulation defects
  - caution with administration and apply pressure to the vaccine site for 1-2 minutes after vaccination





# MenB Vaccine Side effects

#### Very Common (1 in 10)

- Fever (>38°C)
- Tenderness / pain at injection site
- Skin rash
- Irritability
- Vomiting / diarrhoea
- Unusual crying

#### Uncommon (1 in 100 to 1 in 1000)

- High fever (>40°C)
- Seizures (including febrile seizures)
- Eczema

#### Rare (1 in 1,000 to 1 in 10,000)

- Urticaria
- Kawasaki's disease





# MenB Vaccine Paracetamol

- Fever with MenB vaccine is a common side effect
- NIAC recommends all babies are given
   3 doses of paracetamol at the 2 and 4 month MenB vaccines

Liquid Infant Paracetamol (120mgs/5ml)		2 months	4 months
Dose 1	2.5 mls (60mg)	At the time of injection	At the time of injection
Dose 2	2.5 mls	4-6 hours	4-6 hours
	(60mg)	after dose 1	after dose 1
Dose 3	2.5 mls	4-6 hours	4-6 hours
	(60mg)	after dose 2	after dose 2





# MenB Vaccine Paracetamol

- Will reduce the fever by ~ 50%
- If fever persists a further dose of paracetamol may be given
   i.e. 4 doses in 24 hours after vaccination
- If baby unwell or fever persists parents should seek medical advice

#### Paracetamol (NOT Ibuprofen)

- Previously not recommended routinely
- Recent studies show NO evidence of a decrease in the immune response when paracetamol is given with the MenB vaccine and other PCI vaccines
- Recommendation supersedes PIL
- No increase in parental attendance if informed beforehand



Not routinely given at the 12 month MenB vaccination (risk of fever is less)

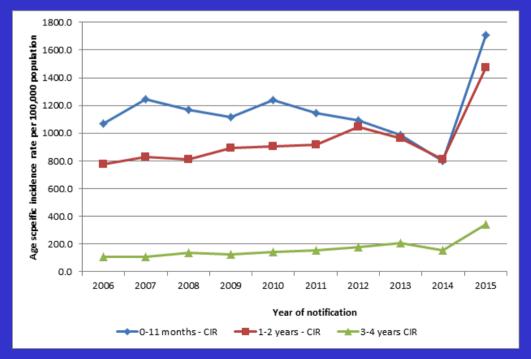


# Rotavirus Disease

- Very common viral infection causing diarrhoea and vomiting
- ~ 2,400 cases notified in Ireland each year
- Most in under 1 year age group

Age specific incidence rate per 100,000 population of notified rotavirus cases

Source HPSC







## Rotavirus Disease

- Estimated that all children infected with rotavirus by age 5
- Spreads very easily through hand to mouth contact and aerosol
- Symptoms
  - ~3-8 days
  - severe diarrhoea, stomach cramps, vomiting, dehydration a low-grade fever
- Most babies and children recover at home
- Every year
  - ~ 920 children aged 0-4 require hospital treatment
  - Average length of stay 5 days





# Rotavirus Vaccine

- Live attenuated ORAL vaccine
- Widely used routinely in Europe, UK, Australia and US
- Can be given with all other PCI vaccines
- Very effective (82-94%) in preventing rotavirus disease in young babies
- Reduces hospital admissions by ~ 70%
- Good safety profile and well tolerated in most babies



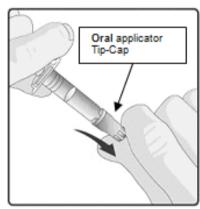




# Rotavirus Vaccine

- Schedule
  - 2 doses at 2 and 4 months
- Give before injected vaccines

#### Instructions for administration of the vaccine:



 Remove the protective tip cap from the oral applicator.



2. This vaccine is for oral administration only. The child should be seated in a reclining position. Administer orally (i.e. into the child's mouth, towards the inner cheek) the entire content of the oral applicator.





# Rotavirus Vaccine Contraindications/ Precautions

#### Contraindications

- Confirmed anaphylactic reaction to a previous dose of rotavirus vaccines or its constituents
- Severe Combined Immunodeficiency Disorder (SCID)
- Previous history of intussusception
- Malformation of the gastrointestinal tract (?lead to intussusception)
- Hereditary fructose intolerance, sucrose-isomaltase deficiency or glucose-galactose malabsorption

#### Precautions (defer until well)

- an acute febrile illness
- an acute vomiting or diarrhoea illness





# Severe Combined Immunodeficiency Disorder (SCID)

- Rare inherited condition =>highly susceptible to infections
- More common in babies in some Traveller families (predominantly but not exclusively from the South East)
- About 1 case every year
- If diagnosed at or shortly after birth can be successfully treated with a bone marrow transplant (in the UK)

#### Need to ask parents

- Are there any diseases in the baby's family that affect the immune system?
- Did anyone in either family need a bone marrow transplant as a baby?



If Yes => FBC required



# Rotavirus Vaccine Intussusception

- Very rare (approx 1 in 50,000 vaccinated babies)
- Intestinal prolapse leading to obstruction
- Most common in those aged 5months 1year
- ~1 in 1000 babies will get this condition naturally
- Symptoms
  - severe abdominal pain
  - worsens with time, 'draw' legs up
  - may get blood in stools, vomiting
- Needs urgent hospital treatment





# Rotavirus Vaccine Schedule

# Two doses at 2 and 4 months of age

- Best protection if given on time
- Increased risk of intussusception with increased age
  - No doses after 8 months and 0 days
  - Minimum interval between dose 1 and 2 is 1 month.
  - Latest time to start dose 1 is 7 months





# Order and site of vaccines

- Give MenB first in LEFT leg
- Give 6 in 1 followed by PCV in RIGHT leg
- To monitor any local adverse reactions
- To give most painful last (PCV)





# Hib/MenC vaccine

- Menitorix (GSK)
- Used in UK PCI schedule
- Single prefilled syringe and vial
- Requires reconstitution







# Information materials

- Information materials for parents
  - Updated
    - maternity leaflet
    - 'Your child's immunisation -A guide for parents'
    - Magnet
    - Immunisation passport
  - New tear pad at 6 weeks
  - Updated
    - tear pad with after vaccine care
    - information on website

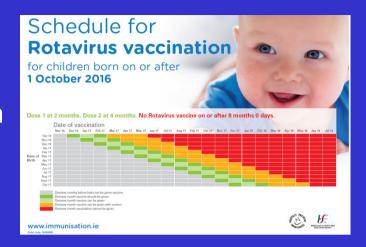






# Information materials

- Train the trainers day 18<sup>th</sup> May, Dublin
- Local roll out of training programme
- Information materials for health care professionals
  - Frequently Asked Questions document
  - Wheel for rotavirus vaccine doses and ages
  - Posters new schedule, rotavirus schedule and paracetamol dosage
  - Updated
    - Guidelines for Vaccinations in General Practice
    - Immunisation Guidelines for Ireland (NIAC)
    - Updated information on website

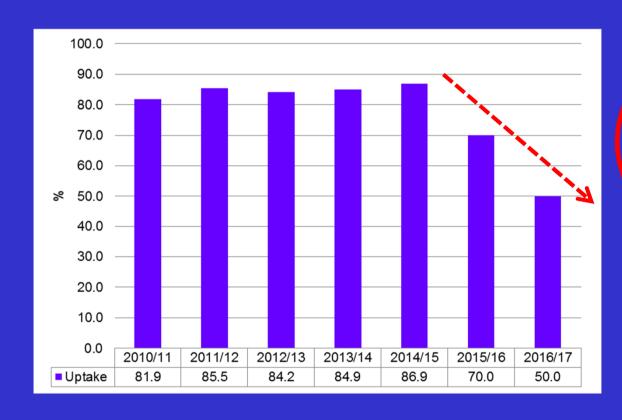








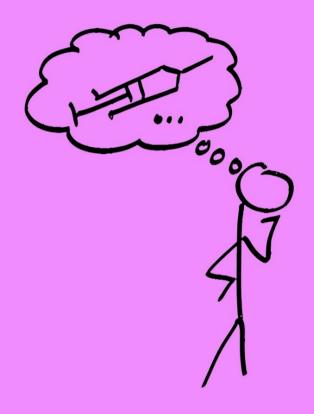
# HPV vaccine uptake 2010/2011 - 2016/2017



5000 more girls not vaccinated in 2015/16







# AREHPV VACCINES SAFE?







A GROUP OF Kerry parents have vowed to continue a campaign to raise awareness on what they believe are the adverse effects of the HPV vaccine - given to young girls to protect them from developing cervical cancer.

BY SINEAD KELLEHER

from Castlemaine, have been raising concerns in Aeneus O'Leary from a campaign since their Aengus O'Leary (left) and Don Myers with the HPV Vaccine leaflet they have produced.

parents. We merely are trying to circulate information on the HPV Vaccine which parents are entitled to.

"We will not tell any parent to vaccinate their child

"We are not anti-vaccine late any information that was not HSE related.

Last Friday, they met with Dr Kevin Kelleher, the assistant national director for public health with the HSE.

Join us on Facebook: For Information here

A Public Service Message from REGRET

HPV vaccination - Do you know the full facts? [31/08/2016]



#### REGRET GoFundMe campaign

[29/06/2016] REGRET GoFundMe campaign begins to help Irish families trying to cope with post-HPVvaccine illness. Tel +353894582901

REGRET and the Aftermath of the HPV Vaccin...

# THE MEANING **OF REGRET**

#### Cervical Cancer Vaccine - Is it safe? (Irish TV3 Documentary)

Four Irish families tell their stories about what getting the HPV Vaccine Gardasil has meant for them. TV3 documentary aired on 14/12/2015.









#### Concerns

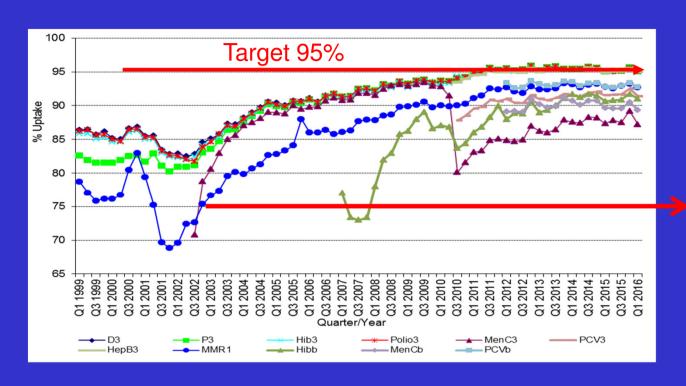


- Vaccine safety
- Vaccine safety
- Vaccine safety
- Vaccine causes serious side effects
- Lack of information
- Consent process too rushed
- Distrust in HSE link to Pharma
- Anti-establishment agenda





# Vaccine uptake rate at 24 months 1999-2016



Measles vaccine linked to autism

- 16 years
- Measles outbreaks
- Death and disability



Reidhmeannacht na Seirbhíse Sláinte Health Service Executive

#### **HPV Vaccine Facts**

#### Cervical Cancer in Ireland

- 6,500 women need hospital treatment pre-cancerous lesions
- > 280 (many young) women need treatment for invasive cancer
- 90 women die

#### Gardasil HPV vaccine prevents cancer developing

#### August 29th 2016 in Australia

• Professor Ian Frazer stated that after ten years of Gardasil HPV vaccine use "the number of new cases of cervical cancer in women has halved" http://www.sciencealert.com/the-hpv-vaccine-has-halved-cervical-cancer-rates-in-the-past-10-years

Best way to prevent cervical cancer = HPV vaccination + cervical screening

- >>> Vaccine prevents precancerous growths and cancer
- >=>> Screening detects pre cancer or cancer of the cervix





### **HPV Vaccine Facts**

# Gardasil HPV vaccine is a safe vaccine with NO known long term side effects

- The safety profile studied for >13 years in >1 million people during clinical trials and since the vaccine was licensed in 2006.
- No increase in the rates of any serious long term condition including autoimmune diseases and chronic fatigue syndrome in vaccinated girls.

  An Overview of Quadrivalent Human Papillomavirus Vaccine Safety: 2006 to 2015, available at: http://www.ncbi.nlm.nih.gov/pubmed/26107345
- Since the programme started in 2010 to 30 September 2016
   HPRA has received 1072 suspected adverse reactions/events
  - most of these reports are expected side effects
  - 14 chronic fatigue syndrome
  - 10 post viral fatigue
  - 3 an auto immune condition

Much less than expected





# Chronic fatigue syndrome (CFS)

- known for over 200 years
- is 3-4 times more common in females and younger adolescents
- 10,000 cases in Ireland
- estimated prevalence rate in Ireland 0.2-0.4%
- 220,000 girls vaccinated (660,000 doses)
  - => at least 440-880 cases expected

Reported numbers much lower than expected





# Gardasil side effects

#### 4. Possible side effects

Like all vaccines and medicines, Gardasil can cause side effects, although not everybody gots them.

The following side effects can be seen after the use of Gardasil

Very commonly (more than 1 in 10 patients), side effects found at the injection site include: pain, swelling and redness. Headache was also seen.

Commonly (more than 1 in 100 patients), side effects found at the injection site include: bruising, itching, pain in extremity. Fever and nausea have also been reported.

Rarely (less than 1 in 1000 patients): hives (urticaria).

Very rarely (less than 1 in 10,000 patients), difficulty breathing (bronchospasm) has been reported.

When Gardasil was given with a combined diphtheria, tetanus, pertussis [acellular, component] and poliomyelitis [inactivated] booster vaccine during the same visit, there was more headache and injection-site swelling.

Side effects that have been reported during marketed use include:

Fainting, sometimes accompanied by shaking or stiffening, has been reported. Although fainting episodes are uncommon, patients should be observed for 15 minutes after they receive HPV vaccine.

Allergic reactions that may include difficulty breathing, wheezing (bronchospasm), hives and rash have been reported. Some of these reactions have been severe.

As with other vaccines, side effects that have been reported during general use include: swollen glands (neck, armpit, or groin); muscle weakness, abnormal sensations, tingling in the arms, legs and upper body, or confusion (Guillain-Barré Syndrome, Acute disseminated encephalomyelitis); dizziness, vomiting, joint pain, aching muscles, unusual tiredness or weakness, chills, generally feeling unwell, bleeding or bruising more easily than normal, and skin infection at the injection site.

#### Side effects seen after use

- => Scientific evidence of causation
- pain, redness or swelling in the arm
- headache
- nausea
- a mild fever
- Itchy rash/ hives
- fainting
- serious allergic reactions very rare



=> No scientific evidence of causation





HPV vaccine

## CDC

#### CDC has carefully studied the risks of HPV vaccination.

HPV vaccination is recommended because the benefits, such as prevention of cancer, far outweigh the risks of possible side effects.

#### **Benefits**

#### **Cancer Prevention**

Cervical, vaginal, and vulvar cancer in women

Anal cancer in men and women

Likely penile cancer in men

Likely oropharyngeal cancer in women and men

#### **Potential Risks**

Chance of fainting

Pain, redness, or swelling in the arm where the shot was given

http://www.cdc.gov/vaccinesafety/pdf/data-summary-hpv-gardasil-vaccine-is-safe.pdf







# **HPV** vaccine information

#### **HPV Vaccines and Cervical Cancer**

#### Human papillomavirus (HPV)

- Gardasil has been licensed worldwide since 2006. Gardasil is currently used in over 25. European countries, the United States, Canada, Australia and New Human Papillomavirus (HPV) infection is spread by direct (usually sexual) contact with an infected
- About 80% of all women will have a HPV infection in their lifetime usually in their late teens and early 20s.
- earry 20s.

  Most HPV infections clear naturally but some caused by high risk HPV types can progress to cervical cancer.
- Two high risk HPV types (16 and 18) cause over 70% of cervical cancers

- By May 2016, over 220 million doses of Gardasil have been distributed worldwide, either as part of national immunisation programmes or by private doctors.
- In Ireland more than 660,000 doses of Gardasil have been distributed and more than 220,000 girls have

- HDV vaccines are more than 90%

#### Do HPV vaccines work?

#### Website accredited by



#### **HPV Vaccine Key Facts**

Cervical cancer

Each year in Ireland

over 90 women die fron cancer

over 280 (many young) women need treatment

(surgery, chemotherap radiotherapy) for invas

cervical cancer over 6 500 women ner

- treatment for a precand form of cervical cancer. There are three licensed H vaccines, HPV2, HPV4 and
- HPV vaccine is recommended the World Health Organisthe International Federal
- in Ireland.

  The HPV vaccine used in t school HPV vaccination pr is HPV4 (Gardasil).

  Gardasil provides protecti
- two high risk HPV types 16 and 18) that cause 7 incers and precancer two HPV types that cau genital warts.

 Human Papillomavirus (HPV) infection is the most common sexually transmitted disease

worldwide

- Spread by direct (usually sexual)
- About 80% of all women will have a HPV infection in their lifetime usually in their late teens and early
- HPV infection rates are rising rapidly among women and men
- in high income countries. · Most HPV infections clear naturally
- . Two high risk HPV types (16 and 18) cause over 70% of cervical cancers.

#### Cervical cancer

- rates of cervical cancer in Western Europe.
- over 90 women die from
- over 280 (many young) women need treatment (surgery, chemotherapy and/ or radiotherapy) for invasive cervical cancer
- over 6.500 women are diagnosed with high grade cervical intraepithelial neoplasia (CIN)

- HDV is responsible for

- types can progress to cervical

- · Ireland has one of the highest
- · Each year in Ireland
- cervical cancer
- and require hospital treatment

#### Human papillomavirus (HPV) Other cancers

- Male incidence of oropharyngeal
- lesions, cervical and anal cancers causally related to HPV types 16 and 18 provides protection against HPV types 6 and 11 that cause over 90% anogenital warts in men

· two dose schedule at 0 and

6 months for girls less than 15 years at first dose

three dose schedule at 0.1.6

. is used in the HSE HPV school

premalignant genital and anal

vaccination programme

• is licensed to prevent

HPV4 vaccine (Gardasil)

months for females age 15 to

- and women · is licensed for use in females
- 6 months for those less than 15 years at first dose

#### **HPV Vaccine**

- Should be administered before exposure to HPV at sexual contact
  - · Recommended for all girls age
  - HPV vaccine is known to be most effective when given at this age. . Two HPV vaccines (HPV2 and
  - HPV 4) were licensed in 2006.
  - HPV2 vaccine (Cervarix) · is licensed to prevent premalignant genital lesions and
  - is licensed for use in female.

- more than 90% anal cancers almost 70% vaginal and vulvar
- more than 60% of penile cancers
- over 70% oropharyngeal cancers.
  - - and males from 9 years of age two dose schedule at 0 and

    - three dose schedule at 0,2, 6 months aged 15 to 26 years.

- HPV9 vaccine (Gardasil 9) was licensed in 2014
- provides protection against 9 HPV types 6.11. 16. 18. 31. 33. 45, 52, and 58 (7 of which cause almost 90% of cervical cancers).

#### **HPV Vaccine Facts**



7 out of 10

cervical cancers

can be prevented with HPV vaccine.



Please read the facts below or download facts about HPV vaccine (596KB)

#### Gardasil HPV vaccine prevents cancer developing.

Some HPV infections caused by high risk HPV types can progress to pre cancerous growths and some of these can progress to cervical cancer.

Gardasil HPV vaccine has been scientifically proven to prevent the HPV infection that causes

In countries with high HPV vaccine uptake such as Australia and Scotland precancerous growths of the cervix have been reduced by more than 50%.

On August 29th 2016, Australian Professor Ian Frazer stated that after ten years of Gardasil HPV vaccine use "the number of new cases of cervical cancer in women has halved"in Australia

Impact and Effectiveness of the Quadrivalent Human Papillomavirus Vaccine: A Systematic Review of 10 Years of Real - world Experience - on the benefits of the HPV vaccine is available at

#### Human Papillomavirus (HPV) Vaccine

- Information > Public Information > Born on or after 1 October 201
- Born on or before 30 September 2016
- > School Programme
- > HPV.ie
- > HPV Vaccination Programm

- > MenC
- > Vaccines & Pregnancy
- > Healthcare Worker Informat
- > Glossany
- > What's new > Contact Us

#### The HSE has offered the HPV vaccine to all girls in first year in second level schools since 2010 to protect them from cervical cancer in adulthood. HPV vaccine is offer to this age group because the response to the vaccine is best at this age.

- > the International Federation of Obstetricians and Gynaecologists

- To read more about HPV please visit the following page > HPV and cervical cancer
- > HPV vaccine
- > HPV vaccine safety

#### Share: 🔳 🕈 💆 🔇 0 HPV vaccine protects against cervical cancer

side effects of Gardasil HPV vaccine

a injection site, headache, fever, nausea

fection with the HPV virus types 6, 11, 16 and 18 for at least 9

s expected to provide life time protection from these viruses

'ely bronchospasm".

11 in every million cases. This is treated by an injection



#### Why is HPV Vaccine Important?



the cervix, 300 women get cervical cancer, and 90 women die from it. Cervical Cancer is caused by HPV.



www.hpv.ie













International Federation of Gynecology and Obstetrics

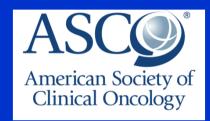


Australian Government

Department of Health Therapeutic Goods Administration









EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH







versus







# Key points

- New PCI schedule for babies born on or after October 1<sup>st</sup> 2016
- 3 doses of infant paracetamol at and after 2 and 4 month Men B vaccines to reduce fever
- No dose of rotavirus after 8 months
- Concerted actions needed to overcome HPV vaccine safety concerns and prevent cervical cancer



